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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/706,321

11/12/2003

Michael Wandell

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EXAMINER

RAMILLANO, LORE JANET

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

12/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/706,321	Applicant(s) WANDELL ET AL.	
	Examiner Lore Ramillano	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 22-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☒ Claim(s) 4, 6, 8, 11, 17, 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/12/03 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/6/06, 9/8/06, 10/3/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Applicant's reply filed on 10/3/07 is acknowledged. Claims 1-41 are pending. Claims 22-41 are withdrawn. Claims 1-21 (Group I) are under examination.

Election/Restrictions

2. Applicant's election of claims 1-21 (Group I) in the reply filed on 10/3/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 22-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Priority

4. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/374,629, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. In this cited application, it appears that this application does not provide support for the following recited subject matter: a fluid collector

comprising an absorbent substrate coated with a saccharide, comprising a mat of glass fibers at least substantially coated with polyvinyl alcohol, the fibers defining a plurality of pores, the pores in the mat having a pore size effective to at least substantially prevent lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking; and the average pore size defining a fluid removal rating of 1.7 micron.

5. Furthermore, because it appears that the disclosure of the prior-filed application, Application No. 10/421,086, provides adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. for one or more claims of this application, this application may obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Therefore, based on the disclosure of the prior-filed applications, as cited, applicant will be given the benefit of the filing date of Application No. 10/421,086, which is 4/23/03.

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on 1/6/06, 9/8/06, and 10/3/07 are acknowledged. Accordingly, the information disclosure statements are being considered by the examiner.

Drawings

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “**dessicant pouch**” (1104) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing

sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

8. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: **1101 in fig. 11; and 901 in fig. 9**. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

9. Claims 4, 6, 8, 11, 17, and 20 are objected to because of the following informalities:

Claims 4, 6, 8, 11, 17, and 20 are objected to because the preamble of these claims should recite, "a kit" since the fluid collector and the fluid collection device are part of the kit.

Claims 4, 6, 8, 11, 17, and 20 are objected to because applicant should recite the limitations associated with device it is referring to, i.e. in claim 4, applicant should recite the limitations associated with the fluid collector, instead of reciting, "the fluid collector of claim 1."

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the subject matter of the invention does not appear to be clearly recited. Does applicant intend to claim that the "absorbent substrate" is coated with two different layers, the saccharide and the polyvinyl alcohol?

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. **Claims 1-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Quattrocchi (US 6014438) in view of Fitzgerald et al. ("Fitzgerald," US 6528321).

In figs. 1-4B, Quattrocchi discloses a fluid collector comprising an absorbent substrate and a superstrate, said fluid collector being generally fixed with respect to said superstrate, said superstrate having an aperture defining a blood receiving opening and permitting access to said fluid collector. The fluid collector having a first end and a second end, said aperture permitting fluidic access to said first end of said collector, said superstrate having a second aperture

relatively proximal said second end of said fluid collector. (i.e. column 5, line 65 to column 8, line 36).

Quattrocchi further discloses a fluid collection device comprising a pair of fluid collectors, and a single superstrate, said fluid collectors ordinarily not being in fluidic contact with one another and each being generally fixed with respect to said superstrate, said superstrate having a pair of apertures, each defining a blood receiving opening and permitting access to a respective one of said fluid collectors. The superstrate comprises a second pair of apertures, each of said fluid collectors having a first end and a second end, said blood receiving openings permitting respectively fluidic access to the first end of one of said fluid collectors, said second pair of apertures each being respectively relatively proximal said second end of one of said fluid collectors thereby defining a pair of gangs. (i.e. column 5, line 65 to column 8, line 36).

Quattrocchi further discloses a kit comprising the fluid collection device and instructions for using the collection device. The instructions being integral with said device, or the instructions being separate from said device. The kit further comprises a requisition form, said requisition form permitting indication of the type of test to be conducted on the fluid to be collected by the device. The requisition form listing a plurality of test types. The kit further comprises a dessicant comprising silica, said dessicant being present in an amount effective to provide a dessicating protective effect on a blood fluid specimen. The dessicant is contained in a porous pouch. Furthermore, the kit comprises a lancet and a barrier film pouch sized to receive said fluid collection device. The barrier film pouch comprises a laminar structure that includes a polyester film and an aluminum foil film, and at least one self-sealing device. (i.e. column 5, line 65 to column 8, line 36).

Quattrocchi does not specifically disclose a substrate comprising a mat of glass fibers and is coated with xylose and polyvinyl alcohol. Fitzgerald discloses a device 100 comprising a first opposable component 102 and a second opposable component 104. The first opposable component 102 has a sample application zone 106 that contains a matrix of porous material permeable to the liquid portion of blood but capable of trapping the cellular components of blood. The first opposable component 102 also includes a chromatographic medium 108 having a first end 110 and a second end 112. The chromatographic medium 108 includes a detection zone 114, a conjugate zone 116, and optionally a control zone 118. These zones are located on the chromatographic medium 108 so that the conjugate zone 116 is located closer to the first end 110 of the chromatographic medium 108 than is the detection zone 114. The control zone 118, if present, is located furthest from the first end 110 and closest to the second end 112 of the chromatographic medium 108 of the three zones. (i.e. column 15, lines 35-50). Fitzgerald discloses that the matrix can be a woven or non-woven fabric, paper, cellulose, glass fiber, polyester, other polymers, or mixtures of these materials to retain the cellular components of blood (i.e. column 17, lines 44-50). Fitzgerald further discloses that the matrix can alternatively be impregnated with a carbohydrate capable of aggregating blood cells, such as mannitol, sorbitol, inositol, .beta.-D-glucose, .alpha.-D-glucose, D(+)xylose, D(+)mannose, D(-)arabinose, L(+)arabinose, D(+)galactose, L(-)xylose, D-glucoheptose, L-lyxose, lactose, maltose, and sucrose (i.e. column 18, lines 37-50). It would have been obvious to a person of ordinary skill in the art to substitute Quattrocchi's substrate for Fitzgerald's substrate, which comprises glass fibers and is coated with xylose and polyvinyl alcohol because it would be desirable to utilize a matrix comprising glass fibers that is capable of trapping the cellular components of the blood

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sample to allow the user to easily assay the blood sample. In addition, it would be desirable to incorporate a carbohydrate, such as xylose, to the matrix since it provides a means for aggregating the blood cells in the sample. (i.e. Fitzgerald, column 17, lines 39-50; and column 18, lines 37-40).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lore Ramillano
Examiner
Art Unit 1797


Jill Warden
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